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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,875	06/21/2006	Ahmed Sheriff	P71167US0	3644

136 7590 11/08/2007

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
11/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,875	SHERIFF ET AL.	
	Examiner	Art Unit	
	Sharon Wen	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-58* is/are pending in the application.

4a) Of the above claim(s) *38,39,41-45,47-55,57 and 58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-37,40,46 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 09/13/2007, has been entered.

Claims 1-26 have been canceled.

Claims 27-58 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I and species of a medicament *without* an additional therapeutically active agent in the Response to Election / Restriction filed on 09/13/2007 is acknowledged. The traversal is on the ground(s) that the species election requirement for a medicament with or without an additional therapeutically active agent is vague and indefinite. This is not found persuasive for reasons stated in the previous Restriction Requirement, mailed 07/13/2007 and reiterated herein for Applicant's convenience.

The present invention lacks a special technical feature because Furue et al. teach a compound that inhibits at least one function of sPLA2 IIA. In the specification, "medicament" is defined as "the carrier, solvent, excipients and salt must be compatible with the active ingredient of the formulation (a compound of at least a molecule, which binds sPLA2 IIA)" (see page 4 of specification). According to this definition, medicament reads on the species *without* an additional therapeutically active agent.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 38-39, 41-45, 47-55 and 57-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic claim.

Claims 27-37, 40, 46 and 56 are currently under examination as they read an antibody which binds or inhibits secretory phospholipase A2 IIA (sPLA2 IIA) and a pharmaceutical composition or a medicament comprising the compound *without* an additional therapeutically active agent.

Applicant is invited to amend the claims to recite the elected species.

Priority

4. The domestic priority date for claims 27-37, 40, 46 and 56 is deemed to be the effective filing date of PCT/EP04/10604 i.e. 09/22/2004.

Applicant's claim for foreign priority is acknowledged. Certified copies of foreign priority application 103 44 204.9 submitted under 35 U.S.C. 119(a)-(d), have been placed of record in the file. The foreign priority application appears to have support for claims 27-37, 40, 46 and 56.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on 04/06/2006, 05/02/2006, 05/19/2006, 07/17/2006, 08/30/2007 are acknowledged and being considered by the examiner.

Specification

6. Applicant is requested to review the application for any spelling error, use of trademarks, embedded hyperlinks and/or other form of browser-executable code.

Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

7. The specification is objected to as **failing to provide proper antecedent basis for the claimed subject matter**. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Applicant is requested to identify the written support for the previously presented claim 34 particularly the claimed limitation of "**humanized immune system**" which also appeared in the original claim, claim 6, which has now been canceled. Applicant is invited to amend the specification to provide antecedent basis for the claimed subject matter.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any New Matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 112 second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claim is indefinite for the recitation "a humanized (with a humanized immune system) vertebrate" because one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of "humanized vertebrate".

The state of the art indicates that XenoMouse strains can produce human antibody (see Green, *Jonurnal of Immunological Methods* 1999 231:11-23, see entire document) and humanized antibodies are genetically engineered antibodies comprising CDRs or rodent origin embedded in the human framework regions and human Fc region. However, it is unclear whether the antibody produced by the "humanized vertebrate" of the present invention is a human or humanized antibody. Therefore the metes and bounds of the instant claim are ill-defined and ambiguous.

Furthermore, the recitation "humanized immune system" renders the claim indefinite because, while it appears to be a product-by-process limitation, i.e., humanized vertebrate produced by humanizing the immune system, it is ambiguous to one of skill in the art whether the "immune system" reads on a non-human animal immune system or a human immune system.

In addition, Applicant is invited to avoid the use of parentheses by amending the claim to recite "a humanized vertebrate with a humanized immune system".

For the purpose of examination, the instant claim reads on *the monoclonal antibody is obtainable by immunizing a humanized non-human vertebrate.*

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any New Matter. See MPEP § 714.02 and 2163.06.

Claim Rejections - 35 USC § 112 first paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 27-37, 40, 46 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is insufficient written description of the genus encompassed by the recitation of "**parts of** sPLA2 IIA".

There is insufficient written description of the claimed genus of "**parts of** sPLA2 IIA" in the absence of defining the relevant identifying characteristics such as the structure of other physical and/or chemical characteristics of the claimed genus.

The instant specification describes the sPLA2 IIA is a marker of systemic inflammatory activity (see page 2 of specification) and that "sPLA2 IIA" includes human sPLA2 IIA (see page 1 of specification).

The specification as filed does not provide written description for any **parts of** sPLA2 IIA broadly commensurate in scope with the claimed invention.

There is insufficient written description to lead a person of skill in the art to know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences for identifying sPLA2A IIA indicated above and disclosed in the specification as filed.

A person of skill in the art was not in possession of the breadth of claimed "parts of sPLA2 IIA" because it was well known in the art at the time the invention was made that molecules with sequence similarity often have different functions.

For example, Attwood (*Science* 290: 471-473, 2000) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences.

Similarly, Skolnick et al. (*Trends in Biotech.* 18: 34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C § 112, paragraph 1 "Written Description" requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January, 2001, See especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.) Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision. (See page 1115.)

12. Claims 34, 46 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

With regards to the instant claims, their breadth, the state of the prior art, and the lack of guidance provided by the inventor, comprise the primary issues as regards the unpredictability of the claimed method.

A) Claim 34 is directed to a monoclonal antibody obtainable by immunizing a humanized vertebrate. Given the broadest reasonable interpretation, the present claim reads on a genus of humanized vertebrates. The instant specification disclosed one species of humanized vertebrates, i.e., humanized mice and/or immune defective mice repopulated with vital immune cells of human origin (see page 5 of specification). The specification does not adequately teach how to effectively make humanized mice or to use the humanized mice commensurate to the scope of the claimed invention, i.e., to obtain monoclonal antibody by immunizing the humanized mice.

State of the art indicates that, at the time of invention, humanized mice models are highly unpredictable. For example, Macchiarini et al. teach that studies with humanized are limited because a number of practical limitations still prevent the models from serving as fully faithful paradigms of human system (*JEM* 2005, 202:1307-1311, see entire document, in particular, page 1310, middle column, Limitations and possible solutions). Furthermore, the state of the art on humanized mice model does not appear to suggest the immunizing the humanized mice for the production of antibody commensurate with the scope of the instant claim.

In view of unpredictability of the art at the time of filing and lack of working model provided by the instant specification, one of skill in the art would not have been enable, at the time of filing, to make the monoclonal antibody by immunizing a humanized mice or any other vertebrate commensurate with the scope of the instant claim without undue experimentation.

B) Claims 46 and 56 are directed to a pharmaceutical composition a medicament comprising an antibody that binds or inhibits sPLA2 IIA. However, the specification does not enable one of skill in the art at the time the invention was made to use the pharmaceutical composition or the medicament for treatment and prevention of the various disease broadly encompassed by the claims and consistent with the instant specification on page 7.

Pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of *Ex parte Aggarwal*, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

The specification does not adequately teach how to effectively treat or prevent any disease or reach an appropriate beneficial therapeutic endpoint in humans by administering an anti-sPLA2 IIA antibody. The specification does not teach how to extrapolate data obtained from various in vitro or in vivo observations with the pharmaceutical composition comprising the antibody to the development of effective methods of treating or preventing human diseases such as osteo- and rheumatoid arthritis, multiple sclerosis, Graves' disease, and the like broadly encompassed by the claimed invention and consistent with the disclosure of various diseases and disorders disclosed on page 7 of the instant specification.

According to *The Merck Manual of Diagnosis and Therapy*, the precise causes of rheumatoid arthritis, a species of autoimmune disease disclosed in the instant specification (see page 7 of the specification), is unknown. While many factors, such as smoking or viral infections, are thought to play a role, a genetic predisposition has been identified in a certain population to contribute to the chronic autoimmune manifestation (*The Merck Manuals Online Medical Library,* [online]. Whitehouse Station, NJ: Merck Research Laboratories, 2006-2007. [retrieved on 10/09/2007]. Retrieved from the Internet: < URL: http://www.merck.com/mmpe/print/sec04/ch034/ch034b.html>. Rheumatoid Arthritis (RA), see pages 1-9). However, the instant disclosure does not provide sufficient in vitro or in vivo evidence showing the administration of a pharmaceutical composition comprising an antibody that binds or inhibits sPLA2 IIA can counter-act the cause or the manifestation of rheumatoid arthritis as defined by *The Merck Manual of Diagnosis and Therapy* in order to treat or prevent the disease.

Also, it is noted that experimental protocols usually are conducted under defined conditions wherein the antagonist and the stimulus / insult occur at the same or nearly the same time. Enzyme inhibition is much easier to achieve under such controlled conditions than that experienced in the human disorders or diseases such as rheumatoid arthritis targeted by the claimed invention (see pages 12-14 of the instant specification).

In view of the lack of predictability of the art to which the invention pertains the lack of established clinical protocols for effective methods to treat or prevent the scope of various diseases disclosed and in view of lack of sufficient working examples provided by Applicant of using an antibody that binds or inhibits sPLA2 IIA, undue experimentation would be required to practice the claimed methods of preventing diseases with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed methods are effective for preventing the diseases or disorders encompassed by the claimed methods.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary, the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 27-37, 40, 46 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Mounier et al. (WO 98/55504, cited on IDS, see entire document) as evidenced by Touqui et al. (*Current Molecular Medicine* 2001, 1:739-754, cited on IDS see entire document).

Mounier et al. teach an antibody that binds a human group II secretory phospholipase A2 (hsPLA2 grII) (see Abstract, pages 1, 5 and 5) wherein the antibody is a polyclonal, monoclonal or humanized antibody (see pages 5-6 and claims 11-12 on page 45).

The "hsPLA2 grII" taught by Mounier et al. is another designation for sPLA2 IIA as evidenced by Touqui et al. (see page 740, left column, first full paragraph).

In addition, Mounier et al. teach a pharmaceutical composition or a medicament comprising the antibody wherein the pharmaceutical composition further comprises a pharmaceutically acceptable carrier (see page 7 and claim 13).

Although Mounier et al. is silent on the antibody that "blocks and/or neutralizes at least one function of the sPLA2 IIA, on a cell surface or in a solution, and/or depletes sPLA2 IIA from a solution" *per se*, given the prior art teaching on the antibody which inhibits sPLA2 IIA anticoagulant effect (see e.g., claim 12), one of ordinary skill in the art would have immediately envisaged that the same antibody taught by the prior art would also block and/or neutralize at least one function of the sPLA2 IIA, on a cell surface or in a solution, and/or depletes sPLA2 IIA from a solution because these are inherent property of an anti-sPLA2 II2 antibody.

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Furthermore, the reference does not teach the antibody being a secretory protein, *per se* (claim 40). However, given the prior art teaching on the antibody being a monoclonal antibody, it would be inherent that the antibody is secreted by the hybridoma cell. Therefore, under the broadest reasonable interpretation, the prior art antibody reads on a secretory protein.

Moreover, claims 32-36 are product-by-process claims because of the recitation "obtainable by immunizing". Since the reference teaches a monoclonal antibody that binds or inhibits sPLA2 IIA, the same antibody would also be obtainable by immunizing a transgenic or humanized vertebrate or by a recombinant process.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 27, 30, 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mounier et al. (WO 98/55504, cited on IDS) in view of Touqui et al. (*Current Molecular Medicine* 2001, 1:739-754) and Owens et al. (*Journal of Immunological Methods* 1994, 168:149-165).

Mounier et al. in view of Touqui et al. have been discussed above (see entire documents).

The Mounier reference in view of the Touqui reference does not explicitly teach an anti-sPLA2 IIA antibody that is recombinant and a secretory protein (claim36 and 40).

However, it is well known in the art, at the time of the present invention was made, to make a recombinant antibody as demonstrated by Owens et al (see entire documents). In particular, Owens et al. teach how to make recombinant antibody by expression of engineered antibodies in mammalian cells (see page 157). In addition, Owens et al teach the recombinant antibody is secreted which reads on "secretory protein".

Given the teaching of Mounier in view of Touqui on an antibody that binds and inhibits sPLA2 IIA and teaching by Owens et al. on how to make a recombinant antibody that is secreted in mammalian cells, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to make a recombinant anti-sPLA2 IIA antibody that inhibits sPLA2 IIA because it is making recombinant antibodies is well known in the art, at the time of the invention was made, to the ordinary artisan, as taught by Owens et al. (see page158, right column, last paragraph).

One of ordinary skill would have been motivated to make a recombinant antibody against sPLA2 IIA given the teaching by Owens that recombinant technology is an efficient method of making antibodies that are authentically glycosylated and expressed in high levels from mammalian cells.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Wen whose telephone number is (571) 270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Wen Ph.D.
Patent Examiner
October 25, 2007

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10/29/07